

REMARKS

Claims 1-14, 29, 34, 35, and 38-58 are pending in the application and are the subject of the office action.

Claims 1-6, 8-14, 29, 38-45, 47-55, 57, and 58 stand rejected under Section 102(e) over Ni et al., US Patent 6,124,580. Claims 1-14, 29, 34, 35, and 38-58 stand rejected under Section 103(a) as being unpatentable over Ni et al. As indicated in Applicants' previously filed response and as discussed further below, it is Applicants' position that the Ni et al. patent cannot properly be applied as "prior art" against the claims presented in the instant application. Because of the deficiencies in its first priority application (which Applicants point out in detail in their amendment filed June 2, 2003), Ni et al., the Ni et al. patent cannot be accorded the first priority application filing as an "effective" filing date for prior art purposes.

The Ni et al. patent clearly does not meet the requirements of utility OR enablement, and Applicants respectfully submit that the Ni et al. specification is not compliant with the current guidelines under Section 101 and 112.¹ Applicants note that it is well-settled law that a patent shall have effect under 35 U.S.C. § 102(e) as of a particular date only to the extent that there is a sufficient disclosure under 35 U.S.C. § 112, first paragraph, for the subject matter in question. The Examiner is referred to In re Wertheim, 646 F2d 527, 209 USPQ 554 (CCPA 1981), as well as MPEP 2136.03, sub-heading IV, which provide that the claims of a reference patent must be supported in the manner required by 35 USC 112 in the priority application whose date is relied on to establish the prior art status of the patent. The disclosure of such an application must include a use that supports the claims under Section 112. If it does

¹ It is noted for the record that the type of disclosure contained in the Ni et al. patent is not compliant with the requirements of Section 101 or 112 according to the positions set forth in the reports entitled "Comparative study on biotechnology patent practices - Theme: Nucleic acid molecule-related inventions whose function are inferred based on homology search", which was produced in 2000 under the auspices of Trilateral Project B3b: Mutual understanding in search and examination, and the "Comparative study on biotechnology patent practices - Theme: Comparative study on 'reach-through' claims", which was produced in November 2001, also under the auspices of Trilateral Project B3b: Mutual understanding in search and examination.

not, that application is simply not available as part of the prior art.

Although Ni et al. disclose in their first priority application certain sequence structure information for the molecule they refer to as "TR10", that first priority application merely speculates what the function or activity TR10 might be. The disclosure in Ni et al. relating to what TR10 may be used for or how it may be used is entirely prophetic. In other words, the disclosure of Ni et al.'s first priority application represents nothing more than a "paper" proposal for future research and is not an enabling disclosure for the skilled artisan.

Recognizing the unpredictable nature of this field of technology, without any teaching of a function or activity of the receptor or the identity of a ligand that binds the putative receptor, the disclosure of the reference cannot enable one of ordinary skill. Moreover, Applicants respectfully submit that the first priority application disclosure of Ni et al. is non-enabling for any claims directed to TR10 DNA, TR10 protein or TR10 antibodies. Those skilled in the art readily understood at the time of the filing of Ni et al. that the TNF receptor family (to which the TR10 receptor belongs) is an extensive family whose members have wide and varied biological activities.


Accordingly, Applicants again respectfully request the Examiner to withdraw the rejections under Sections 102(e) and 103(a) in view of Ni et al.

Lastly, Applicants wish to advise that related application serial no. 09/548,815 being handled by Examiner O'Hara, and of which the Examiner is aware, remains pending.

Respectfully submitted,
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Date: January 27, 2004

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